Attachment F

510 (k) Summary of Safety and Effectiveness

APR - 4 2011

Date Summary Prepared: November 11, 2010

Submitter Information: Spinal USA
2050 Executive Drive
Pearl, MS 39208

Contact Name: Linda Polk
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Device Trade Name: Vault ALIF System

Common Name: Intervertebral Body Fusion Device

Regulatory Number: 888.3080
Classification: Class II
Product Code: OVD

INTENDED USE: The Vault ALIF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space.

The Vault ALIF System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used with autogenuos bone graft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device.

The Vault ALIF System is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixations.

DEVICE DESCRIPTION:
The Vault ALIF System consists of implants with various widths, heights, lengths and bone screws to accommodate individual patient anatomy and graft material size. All components are manufactured from medical grade polyetheretherketone (Peek LT1). The products are supplied clean and "NON-STERILE".

MECHANICAL TESTING:
The Vault ALIF System was mechanically tested per ASTM F2077, F2267 and Expulsion. The objectives of this test battery were to mechanically test the Vault ALIF System using the following test methods:

Static testing in a load to failure mode in axial compression
Static testing in a load to failure mode in shear compression
Static testing in subsidence
Static testing in expulsion
Cyclical axial compression testing to estimate the maximum run out load value at 5,000,000 cycles
Cyclical shear compression testing to estimate the maximum run out load value at 5,000,000 cycles

Mechanical Test Conclusion:

The Vault system is as safe as the predicates based on the following:

1) The design of the Vault system is similar to the predicates in height, width, length and lordotic angle.
2) The materials used in the Vault system are the same as used in the predicate systems.
3) The mechanical strength of the Vault system is greater than the predicate based on mechanical test results

The Vault system is as effective as the predicate based on the following:

1) The intended use of the Vault system is the same as the predicates.
2) The indication for use of the Vault system is the same as the predicates.
3) The bone port opening of the Vault system is equivalent to its predicates.

The Vault system is as safe and effective as its predicates.

EQUIVALENT DEVICE:
Documentation was provided which demonstrated the Vault ALIF System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, performance and material of manufacture.

Predicate Devices:
Spinal USA Interbody Fusion Device (K092193)
Solitare Anterior Spinal System (K081501)
STALIF TT Intervertebral Body Fusion System (K073109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Spinal USA
% Ms. Linda Polk
2050 Executive Drive
Pearl, Mississippi 39208

Letter dated: January 23, 2013

Re: K103369
Trade/Device Name: Spinal USA Vault ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: March 14, 2011
Received: March 17, 2011

Dear Ms. Polk:

This letter corrects our substantially equivalent letter of April 4, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103369

Device Name: Vault ALIF System

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Prescription Use X AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K103369